

Listing of the Claims

This listing of claims will replace all prior versions, and listings, of the claims in this application.

Listing of claims:

1. (Previously presented) A method of enhancing an immunogenic response in a mammalian subject, the method comprising administering microparticles of a biodegradable polymer to the mammalian subject, the microparticles comprising a biologically effective amount of one or more antigens, the microparticles also encapsulating one or more basic additives.
2. (Previously presented) The method of claim 30 wherein the antigen is selected from the group consisting of nucleic acids, proteins, polypeptides, peptides, polysaccharides, hapten conjugates, and combinations thereof.
3. (Original) The method of claim 2 wherein the antigen is a peptide.
4. (Previously presented) The method of claim 2 wherein the basic additive is characterized by having a pH of a saturated solution at 37°C in the range from about 6.8 to about 12.5 and a solubility in water at 37°C from 1.2×10^{-2} to about 3×10^{-11} .
5. (Previously presented) The method of claim 2 wherein the basic additive is selected from the group consisting of magnesium carbonate, magnesium hydroxide, magnesium oxide, magnesium trisilicate, zinc carbonate, zinc hydroxide, zinc phosphate, aluminum hydroxide, basic aluminum carbonate, dihydroxyaluminum sodium carbonate, dihydroxyaluminum aminoacetate, ammonium phosphate, calcium phosphate, calcium hydroxide, magaldrate, calcium sulfate and combinations thereof.
6. (Previously presented) The method of claim 2 wherein the mammalian subject is a human.
- 7-26. (Canceled)

27. (Withdrawn) An immunogenic composition for eliciting an immune response against an antigen comprising:

- a) a biodegradable polymeric delivery system;
- b) a biologically effective amount of an antigen; and
- a) a basic additive.

28. (Withdrawn) An immunogenic composition for eliciting an immune response against human chorionic gonadatropin (hCG) comprising:

- a) a poly(lactide-co-glycolide) polymeric delivery system; wherein the ratio of lactide/lactic acid to the ratio of glycolide/glycolic acid is in the range from 100:0 to 50:50;
- b) 0.08 to 20% (w/w) of an hCG antigen, based on the weight of the polymer, wherein the hCG antigen is a carboxyl terminal peptide (CTP) of the beta subunit of hCG; and
- c) 0.5 to 20% (w/w) of a basic additive, based on the weight of the polymer, wherein the basic additive is selected from the group consisting of magnesium carbonate, magnesium hydroxide, magnesium oxide, magnesium trisilicate, zinc carbonate, zinc hydroxide, zinc phosphate, aluminum hydroxide, basic aluminum carbonate, dihydroxyaluminum sodium carbonate, dihydroxyaluminum aminoacetate, ammonium phosphate, calcium phosphate, calcium hydroxide, magaldrate, calcium sulfate and combinations thereof.

29. (Withdrawn) The immunogenic composition of claim 28 wherein the ratio of basic additive to antigen is about 4:1.

30. (Previously presented) The method of claim 1, wherein the one or more antigens are encapsulated in the microparticles, conjugated to the microparticles, or both.

31. (Previously presented) The method of claim 30, wherein the one or more antigens are encapsulated in the microparticles

32. (Previously presented) The method of claim 30, wherein the one or more antigens are conjugated to the microparticles.

33. (Previously presented) The method of claim 30, wherein the antigen is an hCG antigen whereby an immunogenic response to human chorionic gonadatropin (hCG) in the subject is enhanced.

34. (Previously presented) The method of claim 33 wherein the hCG antigen is a carboxyl terminal peptide (CTP) of the beta subunit of hCG.

35. (Previously presented) The method of claim 33 wherein the microparticles comprises from 0.08 to 20% antigen based on the weight of the biodegradable polymer.

36. (Previously presented) The method of claim 33 wherein the antigen is conjugated to the microparticles and encapsulated in the microparticles.

37. (Previously presented) The method of claim 33 wherein the antigen is conjugated to the microparticles.

38. (Previously presented) The method of claim 33 wherein the antigen is encapsulated in the microparticles.

39. (Previously presented) The method of claim 33 wherein the basic additive is characterized by having a pH of a saturated solution at 37°C in the range from about 6.8 to about 12.5 and a solubility in water at 37°C from 1.2×10^{-2} to about 3×10^{-11} .

40. (Previously presented) The method of claim 33 wherein the basic additive is selected from the group consisting of magnesium carbonate, magnesium hydroxide, magnesium oxide, magnesium trisilicate, zinc carbonate, zinc hydroxide, zinc phosphate, aluminum hydroxide, basic aluminum carbonate, dihydroxyaluminum sodium carbonate, dihydroxyaluminum aminoacetate, ammonium phosphate, calcium phosphate, calcium hydroxide, magaldrate, calcium sulfate and combinations thereof.

41. (Previously presented) The method of claim 40 wherein the basic additive comprises magnesium carbonate.
42. (Previously presented) The method of claim 33 wherein the ratio of basic additive to antigen is from 0.5:1 to 30:1 (w/w).
43. (Previously presented) The method of claim 42 wherein the ratio of basic additive to antigen is about 4:1 (w/w).
44. (Previously presented) The method of claim 33 wherein the ratio of basic additive to biodegradable polymer is from 0.5 to 20% (w/w).
45. (Previously presented) The method of claim 44 wherein the ratio of basic additive to biodegradable polymer is from 1 to 7% (w/w).
46. (Previously presented) The method of claim 33 wherein basic additive is added at a level of 3% or less based on the weight of the biodegradable polymer.
47. (Previously presented) The method of claim 33 wherein the biodegradable polymer is a poly(lactide-co-glycolide) (PLGA) delivery system.
48. (Previously presented) The method of claim 47 wherein the PLGA is poly(D-L-lactide-co-glycolide).
49. (Previously presented) The method of claim 47 wherein the ratio of lactide/lactic acid to the ratio of glycolide/glycolic acid is in the range from 100:0 to 0:100.
50. (Previously presented) The method of claim 49 wherein the ratio of lactide/lactic acid to the ratio of glycolide/glycolic acid is in the range from 100:0 to 50:50.
51. (Previously presented) The method of claim 33 wherein the microparticles further comprise an adjuvant.
52. (Previously presented) The method of claim 33 wherein the microparticles further comprise an excipient.

53. (Previously presented) The method of claim 1, wherein the immunogenic response to human chorionic gonadatropin (hCG) of a human subject is enhanced by administering to the subject an immunogenic composition comprising:

a) a biodegradable polymeric delivery system comprising microparticles of a poly(lactide-co-glycolide) polymer, wherein the ratio of lactide/lactic acid to the ratio of glycolide/glycolic acid in the polymer is in the range from 100:0 to 0:100;.

b) 0.08 to 20% (w/w), based on the weight of the polymer, of an hCG antigen comprising a carboxyl terminal peptide (CTP) of the beta subunit of hCG, wherein the hCG antigen is encapsulated in the microparticles, conjugated to the microparticles, or both; and

c) 0.5 to 20% (w/w), based on the weight of the polymer, of a basic additive selected from the group consisting of magnesium carbonate, magnesium hydroxide, magnesium oxide, magnesium trisilicate, zinc carbonate, zinc hydroxide, zinc phosphate, aluminum hydroxide, basic aluminum carbonate, dihydroxyaluminum sodium carbonate, dihydroxyaluminum aminoacetate, ammonium phosphate, calcium phosphate, calcium hydroxide, magaldrate, calcium sulfate and combinations thereof, wherein the basic additive is encapsulated in the microparticles.

54. (Previously presented) The method of claim 53 wherein the ratio of basic additive to antigen is from 0.5:1 to 30:1 (w/w).

55. (Previously presented) The method of claim 54 wherein the ratio of basic additive to antigen is about 4:1 (w/w).

56. (Previously presented) The method of claim 54 wherein the ratio of basic additive to biodegradable polymer is from 1 to 7% (w/w).

57. (Previously presented) The method of claim 56 wherein basic additive is added at a level of 3% or less based on the weight of the polymer.

58. (Previously presented) The method of claim 54, wherein the basic additive comprises magnesium carbonate.

59. (Previously presented) The method of claim 54 wherein the polymer is poly(D-L-lactide-co-glycolide).

60. (Previously presented) The method of claim 53 wherein the ratio of lactide/lactic acid to the ratio of glycolide/glycolic acid in the polymer is in the range from 100:0 to 50:50.

61. (Previously presented) The method of claim 53 wherein the polymeric delivery system further comprises an adjuvant.

62. (Previously presented) The method of claim 53 wherein the polymer delivery system further comprises an excipient.